K070431

Section 5: 510(k) Summary

MAY 24 2007

1.0 **Submitted By:**

Dave Fliss, President
Welmed, Inc.
691 Lake Street
Grayslake, IL 60030
Establishment Registration Number: 3005841027

Primary Contact:
Glen Feye, President
Accurate Consultants, Inc.
1340 West Pennsylvania Ave.
San Diego, CA 92103
Telephone: 619-291-3695
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glenfeye@earthlink.net

2.0 **Date Submitted:**

February 8, 2007

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Welmed, Inc. Surgical Gowns

3.2 **Classification Name**

21CFR 878.4040 (Surgical Gown)
Product code - FYA (Gown, Surgical).

4.0 Predicate Devices:

Candidate	Predicate	Manufacturer	Docket Number
Welmed Surgical Gowns	IMC Surgical Gowns	International Medsurg Connections, Inc.	K052550

5.0 Intended Use:

Disposable gowns are used in the OR as a protective covering, for operating room staff, from the transfer of body fluids and particulates.

Gowns provided as sterile and non-sterile.

Non-sterile surgical gowns are to be sold to OEMs for EtO sterilization according to ISO 11135. Sterile Surgical Gowns are to be sold directly to users after EtO sterilization validation to ISO 11135.

6.0 Comparison to Predicate(s):

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

Similarities to the Predicate

Product	Aspect/Characteristic	Comments
Welmed Surgical Gowns	Basic Intended Use	Same as IMC Surgical Gowns
	Materials Used – SMMS & SPP	
	Configurations/Design	
	Provided Sterile and Non-Sterile	
	Testing Methods	

There are no significant differences between the Welmed products and their respective predicate products.

7.0 Summary of Performance Data:

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, materials, design and testing methods.

Test Data Provided in this Submission

Standard or Guidance Document	Data Generated	Relevant Section of Submission
AATCC Test Method 127-1998 Water Resistance: Hydrostatic Pressure Test	Hydrostatic Pressure - Water Resistance	18
AATCC Test Method 42-2000 Water Resistance: Impact Penetration Test	Impact Penetration – Water Resistance	18
ASTM - D5034-95(2001) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Tensile Strength	18
ASTM – D5734-95(2001) Standard Test Method for Tearing Strength of Nonwoven Fabrics by Falling-Pendulum (Elmendorf) Apparatus	Elmendorf Tear	18
ISO 9073-10:2003 - Textiles – Test methods for nonwovens – Part 10: Lint and other particles generation in the dry state	Gelbo Flex - Lint	18
CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles	Flammability	18
AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing	Biocompatibility Testing Evaluation	15
AAMI / ANSI / ISO 10993-5:1999, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	Cytotoxicity	15
AAMI / ANSI / ISO 10993-10:2002(E), Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization	Skin Irritation, intra-cutaneous reactivity & sensitization	15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2007

Welmed, Incorporated
C/O Mr. Glen Feye
President
Accurate Consultants, Incorporated
1340 West Pennsylvania Avenue
San Diego, California 92103

Re: K070431
Trade/Device Name: Welmed, Incorporated Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: April 12, 2007
Received: May 8, 2007

Dear Mr. Feye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

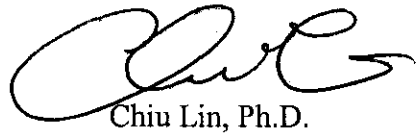
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statements

Indications for Use

510(k) Number (if known): K070431

Device Name: **Welmed Surgical Gowns**

Indications for Use:

Disposable gowns are used in the OR as a protective covering, for operating room staff, from the transfer of body fluids and particulates.

Gowns provided as sterile and non-sterile.

Non-sterile surgical gowns are to be sold to OEMs for EtO sterilization according to ISO 11135. Sterile Surgical Gowns are to be sold directly to users after EtO sterilization validation to ISO 11135.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...k) Number: K070431